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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,507	02/28/2002	Donald G. Munroe	108074-00023	8368

6449 7590 06/03/2003

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/03/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/084,507	Applicant(s) MUNROE ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, drawn to isolated lysolipid (LL) receptor/EDG receptor, classified in class 530, subclass 350.
- II. Claims 3-5, 32, 35-43 drawn to isolated EDG receptor, classified in class 530, subclass 350.
- III. Claims 6, 31, 33, 34, drawn to isolated DNA, vector, host cell, classified in class 435, subclass 69.1.
- IV. Claims 7, 8, 17, 18, drawn to a method comprising contacting cells with compound and measuring a response indicative of the degree of NF-kB activation, classified in class 435, subclass 7.1.
- V. Claims 13, 14, 23, 24, drawn to a method comprising contacting cells with compound and measuring a response indicative of the degree of IL-8 production, classified in class 436, subclass 501.
- VI. Claims 9, 10, 15, 16, drawn to pharmaceutical composition comprising agonist, class dependent on agonist.
- VII. Claims 11, 12, drawn to a method comprising administering a pharmaceutical composition comprising an agonist to a subject for upregulation of inflammatory and immune response, classified in class 514, subclass 2.

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- VIII. Claims 19, 20, 25, 26, drawn to pharmaceutical composition comprising antagonist, class dependent on antagonist.
- IX. Claims 21, 22, drawn to a method comprising administering a pharmaceutical composition comprising an antagonist to a subject for downregulation of inflammatory and immune response, classified in class 514, subclass 2.
- X. Claims 27 and 28, drawn to a method of controlling apoptosis in a cell, classified in class 435, subclass 7.1.
- XI. Claims 29 and 30, drawn to a method comprising determining whether an expressible DNA sequence encodes an EDG receptor, classified in class 435, subclass 7.1.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.06 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups II-III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group III, such as by chemical synthesis, or by isolation and purification from natural sources.

Additionally, the DNA of Group III can be used other than to make the protein of Group II, such in gene therapy or as a probe in nucleic acid hybridization assays.

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Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups IV, V, VII, IX, X, XI are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Invention IV requires contacting cells with compound and measuring a response indicative of the degree of NF-kB activation, which is not required by any of the other groups. Invention V requires comprising contacting cells with compound and measuring a response indicative of the degree of IL-8 production, which is not required by any of the other groups. Invention VII requires administering a pharmaceutical composition comprising an agonist to a subject for upregulation of inflammatory and immune response, which is not required by any of the other groups. Invention IX requires administering a pharmaceutical composition comprising an antagonist to a subject for downregulation of inflammatory and immune response, which is not required by any of the other groups. Invention X requires method of controlling apoptosis in a cell, which is not required by any of the other groups. Invention XI requires determining whether an expressible DNA sequence encodes an EDG receptor. Therefore, a search and examination of all methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and/or the subject matter is divergent.

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Inventions I/IV; II/IV, V, VI, X; III/IV, V, X, XI; VI/VII, X; VIII/IX, X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein products of Groups I and II can be used in processes to make antibodies. The DNA product of Group III can be used in hybridization processes. The processes of modulating inflammatory and immune responses and controlling apoptosis (Groups VII, IX and X) can be practiced with another product.

Inventions I/II, III, V-XI; II/VI-IX, XI; III/VI-IX; IV/VI, VIII; V/VI, VIII; VI/VIII, IX; VII/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and/or have different modes of operation.

Applicant is required to select one polynucleotide sequence (SEQ ID NO:) and one polypeptide sequence (SEQ ID NO:). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Amino acid sequences of different polypeptides are also structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to

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represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Accordingly, only one (1) independent and distinct nucleotide/polypeptide sequence will be examined in a single application without restriction.

This is not a species election but a further election of a group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
May 27, 2003



ELIZABETH KEMMERER
PRIMARY EXAMINER